

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS**

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IN RE YASMIN AND YAZ (DROSPIRENONE) : 3:09-md-02100-DRH-PMF
MARKETING, SALES PRACTICES AND
RELEVANT PRODUCTS LIABILITY : MDL No. 2100
LITIGATION

----- : Judge David R. Herndon

BRENDA MCKIE; DANA MILES;
KAYLA SINGLETARY; SARAH TOLSON; : COMPLAINT AND JURY DEMAND
MELISSA BONHOFF : Civil No.: 3:11-cv-12426-DRH -PMF

Plaintiffs,

vs. :

BAYER PHARMA AG :
and BAYER HEALTHCARE :
PHARMACEUTICALS INC. :

Defendants. :

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COMPLAINT AND JURY DEMAND

Plaintiffs, by and through counsel, and for their Complaint against Defendants, allege as follows:

PARTIES AND JURISDICTION

1. Plaintiff Brenda McKie is a natural person and a resident of the State of North Carolina.
2. Plaintiff Dana Miles is a natural person and a resident of the State of South Carolina.
3. Plaintiff Kayla Singletary is a natural person and a resident of the State of Virginia.

4. Plaintiff Sarah Tolson is a natural person and a resident of the State of Virginia.

5. Plaintiff Melissa Bonhoff is a natural person and a resident of the State of Virginia.

6. Plaintiffs were prescribed and ingested Yasmin[®] and/or YAZ[®], and while using Yasmin and/or YAZ, Plaintiffs suffered injury, including but not limited to, blood clots, stroke, pulmonary embolism, and gallbladder disease. (Yasmin and YAZ are registered trademarks of Bayer AG.)

7. Plaintiffs allege an amount in controversy in excess of Seventy-Five Thousand Dollars (\$75,000), exclusive of interest and costs.

8. Defendant Bayer Pharma AG, formerly known as Schering AG and the same corporate entity as Schering AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Mullerstrasse 178, 13353 Berlin, Germany.

9. Defendant Bayer Pharma AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

10. Defendant Bayer Pharma AG manufactures drospirenone and ethinyl estradiol, the progestin and estrogen contained in its products, YAZ and Yasmin.

11. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Bayer Healthcare Pharmaceuticals, Inc. was created by the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare Pharmaceuticals, Inc. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third

parties or related entities, its products including the prescription drugs Yasmin and YAZ. At all times material hereto, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted regular and sustained business in North Carolina, South Carolina and Virginia by selling and distributing its products throughout the states of North Carolina, South Carolina and Virginia and throughout the United States, including the state of Illinois.

12. Defendants Bayer Pharma AG and Bayer Healthcare Pharmaceuticals, Inc. are collectively referred to herein as “Bayer” or “Defendants.”

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. 1332 and the Judicial Panel on Multidistrict Litigation’s October 1, 2009 Transfer Order and Case Management Order 9 because complete diversity of citizenship exists between the parties and the amount in controversy exceeds \$75,000, exclusive of interests and costs.

14. Venue is proper in the Southern District of Illinois pursuant to the Judicial Panel on Multidistrict Litigation’s October 1, 2009 Transfer Order and Case Management Order 9 for the purposes of pretrial proceedings.

FACTUAL BACKGROUND

Nature of the Case

15. Plaintiffs bring this case against Defendants for damages associated with their ingestion of the pharmaceutical drug Yasmin and/or YAZ (ethinyl estradiol and drospirenone), which is are oral contraceptives designed, manufactured, supplied, marketed, and distributed by Defendants.

16. Specifically, Plaintiff Brenda McKie was diagnosed with deep vein thrombosis on or about January 2002, as a direct result of her use of YAZ and/or Yasmin.

17. Specifically, Plaintiff Dana Miles suffered gallbladder removal surgery on or about April 2007, as a direct result of her use of YAZ and/or Yasmin.

18. Specifically, Plaintiff Kayla Singletary suffered gallbladder removal surgery on or about June 2010, as a direct result of her use of YAZ and/or Yasmin.

19. Specifically, Plaintiff Sarah Tolson suffered gallbladder removal surgery on or about November 6, 2007, as a direct result of her use of YAZ and/or Yasmin.

20. Specifically, Plaintiff Melissa Bonhoff suffered gallbladder removal surgery on or about August 15, 2006, as a direct result of her use of YAZ and/or Yasmin.

Bayer's Combined Oral Contraceptives – Yasmin and YAZ

21. Yasmin and YAZ are birth control pills manufactured and marketed by Bayer. They are combination oral contraceptives, or “COCs,” meaning they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

22. Yasmin and YAZ were approved by the United States Food and Drug Administration (FDA) for marketing in 2006 and 2001, respectively.

Yasmin and YAZ Contain “Fourth Generation” Progestin

23. The estrogen component in Yasmin and YAZ is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and YAZ contains 0.02 milligrams of ethinyl estradiol. Both products contain three (3) milligrams of drospirenone.

24. Yasmin and YAZ are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.

25. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using these pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks and strokes.

26. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

27. During the 1990's new "third generation" progestins were developed. Unfortunately, these third generation progestins (e.g. gestodone and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of the increased risk of blood clots, the FDA has required that these products containing third generation progestins include a warning of the potentially increased risk of thrombosis.

28. Yasmin and YAZ contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.

29. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and YAZ marketed under the trade name Ocella®, manufactured by Teva and a registered trademark of Barr Laboratories, Inc.

30. Unlike second generation progestins, drospirenone in birth control is new, and thus is not supported by decades of data defending its safe use. Studies performed prior to FDA

approval, however, indicate that drospirenone has certain effects that are different and potentially more dangerous than those of traditional second generation progestins.

31. One possible mechanism of action is that drospirenone interacts differently with ethinyl estradiol compared to other progestins, such that it does not sufficiently counterbalance the clotting effects of estrogen as do other progestins, particularly the second generation progestins.

32. Another possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.

33. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

34. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

35. Other effects YAZ, Yasmin and hyperkalemia include substantially increased risks of liver, kidney and gallbladder complications and organ failure.

36. Indeed, during the brief time that Yasmin and YAZ have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

37. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed

in lieu of Yasmin as a result of forty (40) cases of venous thrombosis among women taking Yasmin.

38. In February 2003, a paper entitled “Thromboembolism Associated With the New Contraceptive Yasmin” was published in the *British Medical Journal* detailing a Netherlands Pharmacovigilance Centre report of five (5) additional reports of thromboembolism where Yasmin was suspected as the cause, including two (2) deaths (Kees van Grootheest & Tom Vrieling, Feb. 1, 2003).

39. In fact, in less than a five (5)-year period, from the first quarter of 2004 through the third quarter of 2008, over fifty (50) reports of death among users of Yasmin and YAZ have been filed with the FDA. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in the childbearing years. Some deaths reported occurred in women as young as seventeen (17) years old. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or YAZ.

Over-Promotion of Yasmin and YAZ

40. Defendants market Yasmin and YAZ as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

41. However, because Yasmin and YAZ contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

42. For example, prior to its integration with Defendant Bayer in 2006, Berlex Laboratories promoted Yasmin’s fourth generation progestin, drospirenone, by stating, “Ask about Yasmin, and the difference a little chemistry can make.”

43. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives and issued a warning letter stating, “FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone[.]”

44. The FDA’s warning letter continued by stating that the advertisement failed “to communicate that the potential to increase potassium is a risk” or that “increased serum potassium can be dangerous.”

45. More recently, Defendants advertised that its products Yasmin and YAZ were indicated for treatment of premenstrual syndrome, or “PMS,” as opposed to the more serious condition of premenstrual dysphoric disorder, or “PMDD.”

46. Defendants also advertised that Yasmin and YAZ contained the added benefit of preventing or reducing acne.

47. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yasmin and YAZ for medical conditions beyond the limits of the FDA approval, and adding that “YAZ/Yasmin has additional risks because it contains the progestin, drospirenone...which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems.”

48. The FDA further warned in its October 3, 2008 letter that YAZ/Yasmin “does not result in completely clear skin” and that Defendants’ “TV Ads misleadingly overstate the efficacy of the drug.”

49. Indeed, the FDA felt Defendants' over-promotion of Yasmin and YAZ was so severe that it required Bayer to run new television advertising to correct the previous misleading Yasmin and YAZ advertisements regarding acne and premenstrual syndrome.

50. Bayer ultimately agreed to spend at least \$20 million on corrective television advertisements and to submit all Yasmin and YAZ advertisements to the FDA for advanced screening for the next six years.

Plaintiff's Use of YAZ and/or Yasmin and Resulting Injuries

51. As a result of Defendants' claim regarding the effectiveness and safety of Yasmin and YAZ, Plaintiff Brenda McKie's medical providers prescribed and Plaintiff began using YAZ and/or Yasmin on or around May 2001. Plaintiff Brenda McKie used YAZ and/or Yasmin for approximately five (5) years.

52. As a result of Defendants' claim regarding the effectiveness and safety of Yasmin and YAZ, Plaintiff Dana Miles's medical providers prescribed and Plaintiff began using YAZ and/or Yasmin on or around January 2005. Plaintiff Dana Miles used YAZ and/or Yasmin for approximately two (2) years.

53. As a result of Defendants' claim regarding the effectiveness and safety of Yasmin and YAZ, Plaintiff Kayla Singletary's medical providers prescribed and Plaintiff began using YAZ and/or Yasmin on or around January 2007. Plaintiff Kayla Singletary used YAZ and/or Yasmin for approximately two (2) years.

54. As a result of Defendants' claim regarding the effectiveness and safety of Yasmin and YAZ, Plaintiff Sarah Tolson's medical providers prescribed and Plaintiff began using YAZ and/or Yasmin on or around January 2007. Plaintiff Sarah Tolson used YAZ and/or Yasmin for approximately five (5) years.

55. As a result of Defendants' claim regarding the effectiveness and safety of Yasmin and YAZ, Plaintiff Melissa Bonhoff medical providers prescribed and Plaintiff began using YAZ and/or Yasmin on or around January 2005. Plaintiff Melissa Bonhoff used YAZ and/or Yasmin for approximately two (2) years.

56. As a direct and proximate result of using Yasmin and YAZ, Plaintiffs suffered the injuries described above.

57. Plaintiffs had never suffered the injuries described above prior to each of their diagnoses on the above-mentioned diagnoses dates.

58. Prior to Plaintiffs' use of Yasmin and YAZ, Defendants knew or should have known that use of Yasmin and YAZ created a higher risk of blood clots than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

59. Therefore, at the time Plaintiffs used Yasmin and YAZ, Defendants knew or should have known that the use of Yasmin and YAZ created an increased risk to consumers of serious personal injury, including deep vein thrombosis, pulmonary embolism, heart attacks, stroke, gallbladder disease and even death.

60. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yasmin and YAZ, Defendants failed to adequately warn Plaintiffs and/or their health care providers of said serious risks before Plaintiffs used the products.

61. Had Plaintiffs and/or their health care providers known of the increased risks and dangers associated with Yasmin and YAZ, Plaintiffs would not have used the products and would not have suffered from deep vein thrombosis and/or gallbladder removal surgeries. As a

direct and proximate result of Plaintiffs' use of Yasmin and/or YAZ, Plaintiffs have suffered significant harm, conscious pain and suffering, physical injury and bodily impairment, including but not limited to suffering from deep vein thrombosis and/or gallbladder removal surgeries, and related sequelea requiring hospitalization, recovery therapy, continuing treatment and medical monitoring, which may have caused permanent effects, and which may continue in the future to cause physical effects and damage that will affect Plaintiffs throughout their lifetimes. Further personal injuries suffered by Plaintiffs include, but are not limited to, pain and suffering, bodily impairment, mental anguish and diminished enjoyment of life.

62. Further, as a direct and proximate result of Plaintiffs' use of Yasmin and YAZ, Plaintiffs have suffered significant mental anguish and emotional distress and will continue to suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

63. Plaintiffs have also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate result of Plaintiffs' use of Yasmin and YAZ.

**FIRST CAUSE OF ACTION FOR STRICT PRODUCTS LIABILITY: DEFECTIVE
MANUFACTURING AGAINST ALL DEFENDANTS**

64. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

65. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of Yasmin and YAZ.

66. The Yasmin and YAZ oral contraceptives manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants were defective in

products' manufacture and construction such that products were unreasonably dangerous, were not fit for the ordinary purpose for which products were intended, and/or did not meet the reasonable expectations of an ordinary consumer.

67. The Yasmin and YAZ oral contraceptives manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants were defective in products' manufacture and construction as described at the time products left the Defendants' control.

68. As a direct and proximate result of Plaintiffs' use of Yasmin and YAZ as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiffs suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

69. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION FOR STRICT PRODUCTS LIABILITY: DEFECT IN
DESIGN OR FORMULATION AGAINST ALL DEFENDANTS

70. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

71. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of Yasmin and YAZ.

72. The Yasmin and YAZ oral contraceptives manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants were defective in products' design such that products were unreasonably dangerous, were not fit for the ordinary

purpose for which products were intended, and/or did not meet the reasonable expectations of an ordinary consumer.

73. At the time Defendants manufactured, designed, distributed, sold, and/or supplied the Yasmin and YAZ oral contraceptive into the stream of commerce, a safer, more practical, alternative design was available.

74. The Yasmin and YAZ oral contraceptives manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants were defective in design as described above at the time products left the Defendants' control.

75. As a direct and proximate result of Plaintiffs' use of Yasmin and YAZ as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiffs suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

76. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION FOR STRICT PRODUCTS LIABILITY: DEFECT DUE TO INADEQUATE WARNING AGAINST ALL DEFENDANTS

77. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

78. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of Yasmin and YAZ.

79. The Yasmin and YAZ oral contraceptives manufactured and supplied by Defendants were defective due to inadequate warning or instruction, because Defendants knew

or should have known that the products were unreasonably dangerous in that it created a substantial increased risk of serious bodily harm and death to reasonably foreseeable consumers such as Plaintiffs, and Defendant failed to adequately warn consumers and/or their health care providers of such increased risk.

80. The Yasmin and YAZ oral contraceptive manufactured and supplied by Defendants was also defective due to inadequate post-marketing warning or instruction, because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of Yasmin and YAZ, Defendants failed to provide adequate warning to consumers and/or their health care providers of the products, knowing the products could cause serious injury and death.

81. As a direct and proximate result of Plaintiffs' use of Yasmin and YAZ as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiffs suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

82. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION FOR STRICT PRODUCTS LIABILITY: DEFECT DUE TO
NONCONFORMANCE WITH REPRESENTATIONS AGAINST ALL DEFENDANTS

83. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

84. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of Yasmin and YAZ, and they made representations regarding the character or quality of Yasmin and YAZ.

85. The Yasmin and YAZ oral contraceptive manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product.

86. Plaintiffs justifiably relied upon Defendants' representations regarding the Yasmin and YAZ oral contraceptive when Plaintiffs used Yasmin and/or YAZ for a continual prescribed period.

87. As a direct and proximate result of Plaintiffs' use of Yasmin and YAZ and Plaintiffs' reliance on Defendants' representations regarding the character and quality of Yasmin and YAZ, Plaintiffs suffered personal injuries, economic and non-economic damages, and will continue to suffer such harms, damages, and economic losses in the future.

88. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION FOR STRICT PRODUCTS LIABILITY: DEFECT DUE TO FAILURE TO ADEQUATELY TEST AGAINST ALL DEFENDANTS

89. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

90. Defendants advised consumers and the medical community that Yasmin and YAZ contained the same safety profile as other oral hormonal birth control pills. However, Defendants

failed to adequately test the safety of Yasmin and YAZ versus other oral hormonal birth control pills.

91. Had Defendants adequately tested the safety of Yasmin and YAZ versus other oral hormonal birth control pills and disclosed the results to the medical community or the public, Plaintiff would not have used, and Plaintiffs' physician would not have prescribed, Yasmin and YAZ.

92. As a direct and proximate result of Defendants' failure to adequately test the safety of Yasmin and YAZ versus other hormonal birth control pills, Plaintiffs suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

93. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION FOR NEGLIGENCE AGAINST ALL DEFENDANTS

94. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

95. Defendants had a duty to exercise reasonable care in the manufacture, design, sale, distribution, supply, marketing, and/or placement of Yasmin and YAZ into the stream of commerce, including a duty to ensure that its products did not pose a significantly increased risk of bodily harm and adverse events.

96. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yasmin and YAZ into interstate commerce in that the Defendants knew, or

should have known, that the products caused such significant bodily harm or death and was not safe for use by consumers.

97. Defendants also failed to exercise ordinary care in the labeling of Yasmin and YAZ and failed to issue consumers and/or their health care providers adequate warnings of the increased risk of serious bodily injury or death due to the use of Yasmin and YAZ.

98. Despite the fact that Defendants knew or should have known that Yasmin and YAZ posed a serious increased risk of bodily harm to consumers, Defendants continued to manufacture and market Yasmin and YAZ for use by consumers.

99. Defendants knew or should have known that consumers, such as Plaintiffs, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

100. As a direct and proximate result of Defendants' negligence, Plaintiffs suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

101. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

SEVENTH CAUSE OF ACTION FOR BREACH OF EXPRESS WARRANTY AGAINST
ALL DEFENDANTS

102. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

103. Defendants expressly warranted that Yasmin and YAZ were safe and effective prescription oral contraceptives.

104. The Yasmin and YAZ birth control products manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers who used the products when taken in the recommended dosages.

105. As a direct and proximate result of Defendants' breach of warranty, Plaintiffs suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

106. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

EIGHTH CAUSE OF ACTION FOR BREACH OF IMPLIED WARRANTY AGAINST ALL
DEFENDANTS

107. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

108. At the time Defendants manufactured, marketed, sold, and distributed Yasmin and YAZ, Defendants knew of the use for which Yasmin and YAZ were intended and impliedly warranted Yasmin and YAZ to be of merchantable quality, fitness, and safe for such use.

109. Plaintiffs and Plaintiffs' health care provider reasonably relied upon the skill and judgment of Defendants as to whether Yasmin and YAZ was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.

110. Contrary to the implied warranty, Defendants' products Yasmin and YAZ were not of merchantable quality or safe for their intended use, because they were unreasonably dangerous as described herein.

111. As a direct and proximate result of Defendants' breach of warranty, Plaintiffs suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

112. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

NINTH CAUSE OF ACTION FOR NEGLIGENT MISREPRESENTATION AND/OR FRAUD
AGAINST ALL DEFENDANTS

113. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

114. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yasmin and YAZ and, while engaged in the course of such business, made representations to Plaintiffs and Plaintiffs' physicians regarding the character and/or quality of Yasmin and YAZ for guidance in their decision to select Yasmin and YAZ for Plaintiffs' use.

115. Specifically, Defendants represented that their products were just as safe, and just as effective or more effective, than other birth control products on the market.

116. Defendants' representations regarding the character or quality of Yasmin and YAZ were untrue.

117. Defendants had actual knowledge based upon studies, published reports and clinical experience that its products Yasmin and YAZ created an unreasonable increased risk of serious bodily injury and death to consumers, or should have known such information.

118. Defendants negligently and/or intentionally misrepresented or omitted this information in its products labeling, promotions and advertisements and instead labeled,

promoted and advertised its products as safe and effective in order to avoid economic losses and sustain profits in its sales to consumers.

119. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to their intended recipients, including Plaintiff and Plaintiffs' physician.

120. Plaintiffs and Plaintiffs' physicians reasonably relied to their detriment upon Defendants' misrepresentations and/or omission in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiffs reasonably relied upon Defendants' representations to Plaintiffs and/or Plaintiffs' health care providers that Yasmin and YAZ was just as safe and effective as other types of oral contraceptives for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

121. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations, Plaintiffs suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

122. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiffs pray for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Punitive and exemplary damages;
4. Attorneys' fees, expenses, and costs of this action; and
5. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: July 29, 2011

RESPECTFULLY SUBMITTED,

/s/ Stevie Nichols

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